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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/296,534 04/22/99 HALLOWITZ

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HM12/0718
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EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

7

DATE MAILED:

07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/296,534

Applicant(s)

Hallowitz et al.

Examiner

Robert A. Zeman

Group Art Unit

1645



☒ Responsive to communication(s) filed on May 5, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13, 16, and 17 is/are pending in the application.

Of the above, claim(s) 17 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 and 16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

The amendment filed May 5, 2000 is acknowledged. Claims 1-3, 5-10 and 12 have been amended. Claim 14 has been canceled. Claims 1-13 and 15-16 are pending and currently under examination. Claim 17 remains pending and withdrawn from consideration.

Response to Amendment

Priority

The objection to the specification with regard to the priority statement is maintained for reasons of record. Application No. 09/139,663 is still improperly referred to as Application No. 09/139,633 throughout the specification.

Oath/Declaration

The objection based on the oath or declaration being defective is maintained for reasons of record. The oath fails to identify priority documents by application number and filing date therein.

Specification

The objection to the specification due to the improper use of more than one grammatical tense is withdrawn in light of the file amendment and Applicant's assertion that all examples are in the present tense and hence are prophetic in nature and do not describe procedures that were actually performed.

Art Unit: 1645

Claim Objections

The objection to claims 2, 6-8 and 10 for the use of the plural “claims” when referring to a single claim is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 16 under 35 U.S.C. 112, first paragraph, in light of the Applicant’s assertion and supporting documents indicating that the cell lines in question are all well-known and readily available to the public.

The rejection of claims 1 and 14 under 35 U.S.C. 112, second paragraph, as being vague through the use of the term “capable of” is withdrawn in light of the amendment to claim 1. The cancellation of claim 14 renders the rejection of said claim moot.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague through the use of the term “treating” is withdrawn in light of the amendment thereto.

The rejection of claims 2, 9 and 10 under 35 U.S.C. 112, second paragraph, as being vague due to the confusing method steps recited is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “obtaining sample cell population” is withdrawn in light of Applicant’s assertion that cells can from **any** cell population.

Art Unit: 1645

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “each conjugated to a capture moiety” is withdrawn in light of the amendment thereto.

The rejection of claim 3-5 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “capture moiety” is withdrawn in light of Applicant’s arguments which were persuasive.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “magnetic particles” while claim 5 recites “magnetic bead” is withdrawn in light of the amendment thereto.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “the removing” is withdrawn in light of the amendment thereto.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “tissue is lymphoid” without proper antecedence is withdrawn in light of the amendment thereto.

The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being vague through the use of the phrase “treating the resting with....” is rendered moot by the cancellation of said claim.

Art Unit: 1645

Claim Rejections Maintained

The rejection of claims 1-13 and 15-16 under 35 U.S.C. 103(a) as being unpatentable over Chun et al (Nature Vol. 387, pages 183-188 May 1997) in view of Chun et al.(Nature Medicine Vol. 1 Number 12, pages 1284-1290. December 1995) and Essex et al. (U.S. Patent 4,725,669) and the rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Chun et al (Nature Vol. 387, pages 183-188 May 1997) in view of Chun et al. (Nature Medicine Vol. 1 Number 12, pages 1284-1290. December 1995) and Essex et al. (U.S. Patent 4,725,669) and Chun et al (Journal of Experimental Medicine. Vol. 188 Number 1, July 6, 1998 pp 83-91) are maintained for reasons of record.

Applicant recites the portion of the Office Action (Paper No. 5) which states that “Chung et al. differs from the recited claims in that they do not use anti-gp120 coupled to magnetic beads for the depletion of cells actively infected with HIV or [sic] do they use the appearance of gp120 on the “stimulated” resting cells as the indicator of virus production. Applicant then argues that the results of Chun et al. (1995, 1997 and 1998 references) do not alone, or in combination with Essex et al. disclose or suggest the invention. Applicant argues that Chun et al. test latently infected cells for the ability to produce the intracellular antigen p24. Applicant further argues that Chun et al merely measure the amount of p24 per unit volume but made no correlation between those amounts and cell number. Applicant then argues that Chun et al. utilized a “quantitative viral culture” to **determine the fraction of cells that can be induced to produce infectious virus** and does not provide a direct measure of the number of latently infected cells. Applicant

Art Unit: 1645

further argues that said assay is complicated and labor-intensive and utilizes complicated statistical methods. Applicant then reiterates that the references of Chun et al. are deficient by failing to measure gp120 and that measurement of said polyprotein unexpectedly provides a new value for assessing the status of the disease. Applicant further argues that while there are various indices of HIV infection, knowledge of said indices would not suggest the use of one of them to be useful in measuring latent viral load. Applicant then proceeds to argue that Chun et al. teach away from the present invention since they chose to use the measurement of the p24 antigen and Essex et al. teach away from the claimed invention since they lyse the cells prior to the measuring of gp120. Applicant concludes by stating case law governing analysis under 25 U.S.C. 103(a).

Applicant's arguments filed Paper No. 6 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Chun et al. makes no correlation between the amount of the amount of p24 produced per unit volume and the cell number, Applicant's argument has been fully considered but they are not persuasive. The enumeration of cells within a culture or used in an assay is a standard laboratory procedure. Consequently, the correlation between cell number and the amount of p24 detected would have been obvious since such analysis is standard practice in laboratories around the world.

With regard to Applicant's argument that the "quantitative viral culture" utilized by Chun et al. does not provide a direct measure of the number of latently infected cells but merely

Art Unit: 1645

“determine the fraction of cells that can be induced to produce infectious virus”. Applicant’s arguments have been fully considered and they are not persuasive. As Applicant has pointed out Chun et al. “determine the fraction of cells that can be induced to produce infectious virus”. Since the cells have to be **induced** with PHA to produce infectious virus they are not “actively” infected but are “latently” infected. Consequently, by measuring the fraction of cells that can produce infectious virus, Chun et al. are, in fact, measuring the number of latently infected cells.

With regard to Applicants argument that Chun et al. and Essex et al. teach away from the claimed invention due to the use of p24 by Chun et al. and the lysing of cells by Essex et al., Applicant’s argument has been fully considered and they are not persuasive. As Applicant has pointed out there are many indices of HIV infection, the level of p24 being one of them. Use measurement of any polypeptide that is only produced by the active replication of the HIV retrovirus as a measurement of viral replication would be obvious to one of skill in the art. Additionally, Essex et al., disclose the use of gp120 as an index of HIV infection, Chun et al (Nature Vol. 387, pages 183-188 May 1997) not only disclose the use of the aforementioned “quantitative viral culture”, they disclosed the use of immunohistochemical staining of **intact** cells (see page 183). Applicant has acknowledged that levels of both p24 and gp120 indexes of HIV infection and therefore it would have been obvious to one of skill in the art to use p24 in lieu of gp120.

Art Unit: 1645

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

This application contains claim 17 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.


Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

Robert A. Zeman

July 14, 2000



DONNA WORTMAN
PRIMARY EXAMINER